

## REMARKS

Claims 1-24 were pending in the application. Claims 22 and 24 now standing canceled by the present amendment, and new Claims 25-30 added, Claims 1-21, 23, and 25-30 are now pending.

The amendments to the claims find support in the specification and claims as originally filed. No new matter is added by way of the amendments. The amendments adding the words "related to an individual patient," "related to said patient," recommending treatment related to said patient" and similar wording find support in the specification, for example, at page 5, line 4; page 10, lines 5-6, 9 and 11-13; page 11, lines 4-6 and 26-27; page 12, lines 11-13 and 25-26; and page 29, lines 10-11. The amendments to the claims referring to personal medical history find support in the specification, for example, at page 13, lines 5-6 and page 28, line 26. Diagnosing a physiological condition of patient finds support in the specification, for example, at page 10, line 12; page 11, lines 4-6; page 12, lines 11-12; and page 13, lines 1-6. The amendments to the claims referring to treatments for diagnosed conditions find support in the specification, for example, at page 12, lines 12-13; page 13, lines 14-15; and page 14, line 24. The amendments to the claims referring to recommending treatments for a diagnosed condition of a patient finds support in the specification, for example, at page 10, lines 5-6; page 11, lines 4-6; and page 12, lines 12-13. The amendment to Claim 15 replacing the term "R&D" with "research and development" finds support in the specification as filed, for example, at page 5, lines 9-10.

New Claims 25-30 find support in the specification and claims as originally filed. Support for methods for determining a physiological condition and for recommending a treatment for a living organism, including where the living organism is an animal and where it is a plant, may be found, for example, at page 5, lines 5-8 (particularly at page 5, line 7, identifying "animals and crops information") and lines 18-19; page 11, lines 16-20 and page 12, lines 5-13.

Claim 1 stands objected to as containing a typographical error. Claims 2, 3, 5, 7, 14, 15, 16, 17, and 19 stand rejected under 35 U.S.C. §112, second paragraph.

Claims 1-11, 18, and 20-24 stand rejected under 35 U.S.C. §102(e) as allegedly anticipated by Sabatini et al, U.S. Patent No. 5,966,712 (hereafter "Sabatini").  
Claims 12-17 and 19 stand rejected under 35 U.S.C. §103(a) as allegedly obvious over Sabatini in view of Lipshutz et al, U.S. Patent No. 5,733,729 (hereafter "Lipshutz").

**The Rejections of Claims 2, 3, 5, 7, 14, 16, 17, and 19 Under 35 U.S.C. §112, Second Paragraph**

Claims 2, 3, 5, 7, 14, 16, 17, and 19 stand rejected under 35 U.S.C. §112, second paragraph, as reciting the limitation "the group," allegedly without proper antecedent basis for that term.

Applicants respectfully note that the Markush group is a proper form of claiming elements in the alternative (see, e.g., MPEP 2173.05(h), citing *Ex parte Markush*, 1925 C. D. 126 (Comm'r Pat. 1925), and submit that Claims 2, 3, 5, 7, 14, 16, 17, and 19 as originally filed are in proper Markush group format. However, in order to expedite prosecution of the claims to allowance, and without altering the scope of the claims, Applicants have amended Claim 1 and dependent claims to recite the limitation "the group" as suggested by the Examiner. Accordingly, Applicants believe the rejections of Claims 2, 3, 5, 7, 14, 16, 17, and 19 under 35 U.S.C. §112, second paragraph, to be overcome.

**The Rejection of Claim 15 Under 35 U.S.C. §112, Second Paragraph**

Claim 15 stands rejected under 35 U.S.C. §112, second paragraph, as failing to describe the term "R&D." In order to expedite prosecution of the claims to allowance, and without altering the scope of the claims, Applicants have amended Claim 15 to recite the limitation "research and development" instead of the acronym "R&D." Accordingly, Applicants believe the rejections of Claim 15 under 35 U.S.C. §112, second paragraph, to be overcome.

**The Rejections Under 35 U.S.C. §102(e)**

Claims 1-11, 18, and 20-24 stand rejected under 35 U.S.C. §102(e) as allegedly anticipated by Sabatini et al, U.S. Patent No. 5,966,712 (hereafter "Sabatini").

Anticipation under 35 U.S.C. §102 requires that “every element of the claimed invention be identically shown in a single reference.” *In re Bond*, 910 F.2d 831,832 (Fed. Cir. 1990).

The present invention is directed to systems and methods for the analysis of nucleic acid array hybridization information related to an individual patient for diagnosing a physiological condition of the patient and for recommending treatment for the patient; and for diagnosing a physiological condition of an individual patient and for recommending treatment for the patient. Thus, the present invention discloses systems and methods for diagnosing a physiological condition of a patient and for recommending treatment of a patient that include, among other elements, at least the elements of a Web server that is configured to receive and transmit hybridization information related to an individual patient, a database server configured to perform such functions as storing data comprising personal medical history information, treatments suitable for diagnosed conditions, an application server configured to recognize two classes of users (diagnostic master users and diagnostic users) and to perform functions such as statistical comparison and analysis related to the individual patient, diagnosing a physiological condition of an individual patient, and recommending treatment of an individual patient. However, Sabatini is directed to different subject matter than the present invention, and does not disclose the present invention. Accordingly, Applicants respectfully traverse the rejections of Claims 1-11, 18, and 20-24 over Sabatini.

Sabatini is directed to genomic tools for research and development. For example, Sabatini summarizes its subject matter as follows: “The present invention provides a powerful database tool for drug development and other research and development purposes.” (Sabatini, column 2, lines 10-12.) Sabatini is not directed to, and provides no disclosure relating to, methods or systems for diagnosing a physiological condition of an individual patient or of multiple patients, nor for recommending treatment for an individual patient or multiple patients.

Sabatini does not include any of the following words:

diagnosis, medical, clinical, patient, disease, treatment, therapy

and fails to disclose any patient-related diagnosis or treatment using genetic data or using any other data or any other means. Accordingly, for this reason alone, Sabatini fails to anticipate the present invention.

The Examiner suggests that the term "GI description" at column 30, line 8 of Sabatini is "clinical information associated with hybridization profiles" (paper number 13, page 4, lines 2-4) and "corresponds to the claimed 'clinical information'." However, as stated in Sabatini at column 30, lines 9-10, the term "GI Description" refers to "annotation describing the sequence of a submitted GenBank entry." Thus, the term "GI Description" is not clinical information.

The Examiner suggests that the term "ORF ID" at column 30, line 7 of Sabatini is "statistical information" (paper number 13, page 4, lines 5-6). However, as stated in Sabatini at column 30, lines 7-8, the term "ORF ID" refers to "a unique identifier for an Open Reading Frame on a contig in a given organism library." Thus, the term "ORF ID" is not statistical information.

The Examiner suggests that the Sabatini provides a "statistical summary of patient database" (paper number 13, page 4, lines 15-18), citing Sabatini at column 16, lines 2-4: "HitDataSource field which identifies the external Genbank datasource of the HitID used to annotate an ORF in a library." It is clear that the cited passage discusses manipulation of data related to an open reading frame in a library. However, nothing in the cited passage relates to a patient, a patient database, or a statistical summary of patient data or a patient database. As discussed above, Sabatini nowhere discusses patients or data related to patients.

The Examiner suggests that the Sabatini provides a "patient genetic pattern database" (paper number 13, page 5, lines 1-2), citing Figure 2A of Sabatini. However, the "Genomic DB" illustrated in Figure 2A of Sabatini as explained in Sabatini, column 12, lines 60-67 and column 13, lines 2-6 is not a patient genetic database, and nowhere discusses a patient database.

In addition, applicants respectfully disagree with the Examiner's suggestion that accessing GenBank is a "business function" (page 3, paragraph 6 a of paper number 13).

The Examiner suggests that Sabatini discusses "determining the physiological condition suggested by said analyzed data" citing Sabatini at column 31, lines 6-7 (paper number 13, page 8, lines 4-9). As explained by the Examiner, "Sabatini at column 31, lines 6-7, teaches from the output result, the user can determine which organism like harbor genes similar those he or she is investigating." As is clear from this passage, Sabatini fails to discuss diagnosing a physiological condition of an individual patient as required by the claims of the present invention. Accordingly, failing to provide elements of the claimed invention, Applicants submit that Sabatini fails to anticipate the present invention.

Accordingly, Applicants believe the rejections of Claims 1-11, 18, and 20-24 under 35 U.S.C. §102(e) to be overcome.

#### **The Rejections Under 35 U.S.C. §103(a)**

Claims 12-17 and 19 stand rejected under 35 U.S.C. §103(a) as allegedly obvious over Sabatini in view of Lipshutz et al, U.S. Patent No. 5,733,729 (hereafter "Lipshutz").

In order to establish a prima facie case of obviousness, there must be: 1) some suggestion or motivation in the art or in the knowledge generally available to one of ordinary skill in the art, to modify or to combine the reference teachings; 2) there must be a reasonable expectation of success; and 3) the prior art references must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, and not based on the Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Sabatini fails to provide an optical scanning system (paper number 13, page 9, lines 19-20). Lipshutz is presented by the Examiner to make up this lack. However, Sabatini lacks elements of the present invention which are not supplied by Lipshutz.

Applicants note that Lipshutz, like Sabatini, does not include the words diagnosis, medical, clinical, patient, disease, treatment, or therapy. Applicants respectfully traverse the rejections of Claims 12-17 and 19 under 35 U.S.C. §103(a).

With respect to Claim 12, the Examiner lists elements said to be provided by Sabatini and suggests that Lipshutz supplies the missing element of "an optical scanning system." However, Claim 12 depends from Claims 1 and 8, and so requires all the elements of those claims. As discussed above, the present invention discloses systems and methods for diagnosing a physiological condition of a patient and for recommending treatment of a patient. Sabatini and Lipshutz combined fail to provide at least the elements of a Web server that is configured to receive and transmit hybridization information related to an individual patient, a database server configured to perform such functions as storing data comprising personal medical history information, treatments suitable for diagnosed conditions, an application server configured to recognize two classes of users (diagnostic master users and diagnostic users) and to perform functions such as statistical comparison and analysis related to the individual patient, diagnosing a physiological condition of an individual patient, and recommending treatment of an individual patient.

Similarly, Sabatini and Lipshutz together fail to provide all missing elements of Claims 13, 14, 15, 16, 17 and 19.

Moreover, there is no motivation or suggestion in the Sabatini reference or in the Lipshutz reference to combine these references to provide these missing elements. Lacking any motivation or suggestion in the references to combine the references to provide the missing elements, the references also fail to provide one of ordinary skill in the art with a reasonable expectation of success for such a combination. Accordingly, failing to provide all the elements of the claimed invention, failing to provide any motivation to be combined to provide the present invention, and failing to provide any reasonable expectation of success for such a combination, Applicants submit that the rejections of Claims 12-17 and 19 under 35 U.S.C. §103(a) is overcome.

### **The Objection to Claim 1**

Claim 1 stands objected to as containing a typographical error. As suggested by the Examiner, in order to clarify the meaning of the claim, and without altering the scope of the claim, the words "data analyses" have been amended to be "data analysis." Accordingly, Applicants believe the objection to claim 1 to be overcome.

### **CONCLUSION**

Applicants respectfully requests consideration and allowance of all pending claims. The Examiner is invited to contact the undersigned attorney at the telephone number indicated below should he find that there are any further issues outstanding.

Please charge any fees, including fees for extension of time, or credit overpayment to Deposit Account No. **08-1641** referencing Attorney's Docket No. **25527-0005**.

Respectfully submitted,

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